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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,429	08/04/2000	Mark S. Dennis	P1639R1	1618

7590 02/11/2003
Genentech Inc.
Attn: Jeffrey S. Kubinec
1 DNA Way
South San Francisco, CA 94080-4990

EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/11/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/632,429

Applicant(s)

DENNIS, MARK S.

Examiner

Sheridan K Snedden

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-26 are cancelled; Claims 1-18 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 13 is/are rejected.
- 7) ☒ Claim(s) 1-11, 14-18 and 27-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of invention I, claims 1-18 and 27-31 is acknowledged. Applicant's cancellation of claims 19-26 is acknowledged. Election was made **without** traverse in Paper No.

9. Claims 1-18 and 27-31 are pending.

2. The restriction requirement set forth in Paper No. 8 called for the election of a peptide by SEQ ID NO. During a telephone conversation with Jeffrey Kubinec on January 8, 2003 a provisional election was made to prosecute SEQ ID NO: 4 in conjunction with Invention I. Affirmation of this election must be made by applicant in replying to this Office action. This selection of the peptide by SEQ ID NO is not a species election.

Drawings

3. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

Specification

4. The disclosure is objected to because of the following informalities: The margins of the specification and claim sheets are inappropriate. Applicant is directed to the MPEP § 1.52,

Language, paper, writing, margins, compact disc specifications, which states the following:

Either 21.0 cm by 29.7 cm (DIN size A4) or 21.6 cm by 27.9 cm (8 1/2 by 11 inches), with each sheet including a top margin of at least 2.0 cm (3/4 inch), a left side margin of at least 2.5 cm (1 inch), a right side margin of at least 2.0 cm (3/4 inch), and a bottom margin of at least 2.0 cm (3/4 inch);

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 27-31 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1,2, 15-18 (and therefore dependent claims 3-14 and 27-31) are indefinite for being directed to non-elected subject matter. As per the restriction requirement set forth in Paper No. 6, Applicant elected SEQ ID NO: 4. Claims 1(ii and iii), 2(ii and iii) recite a peptide that competes with the peptide defined as SEQ ID NO: 4 and not the peptide defined as SEQ ID NO: 4. Likewise, claims 15-18 recite peptides that are not the peptide of SEQ ID NO: 4.

7. Claims 12-14 are indefinite for being of improper dependent form for failing to further limit the subject matter of a previous claim. As recited, claims 12-14 would define a class of peptides, whereas the parent claim is directed to a single peptide defined by the sequence of SEQ ID NO: 4. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1653

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Vlasuk *et al.* (US Patent 6,087,487). Vlasuk *et al.* teach peptide AcaNAP5 with comprises a NAP domain with the sequence Xi-Cys-Xj-Cys-Xk as recited in claim 12 (see Figure 16, SEQ ID NO: 40, claim 1, columns 65-66, and table 1). For AcaNAP5, Xi is 62, Xj is 5 and Xk is 8. Vlasuk *et al.* also describes a general formula I for the Nap domains (see column 12). Formula I would read upon claim 13 where Xi and Xk are between 1 and 50. Vlasuk *et al.* teach that AcaNAP5 has Factor Xa inhibitory activity with a Ki of 43 pM, which would correlate to a IC50 of less than 5 nM (see claim 1 and columns 65-66 and table 1; regarding claims 12 and 13). Thus, the reference anticipates the claimed invention.

Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Orning *et al.* A peptide sequence from the EGF-2 like domain of FVII inhibits TF-dependent FX activation. Thrombosis Research (1997), 86(1), 57-67. Orning *et al.* teach peptides of the formula Xi-Cys-Xj-Cys-Xk, which inhibit FX activation.

Hemberger *et al.* (US Patent 5,583,111) teach a peptide defined by the formual Xi-Cys-Xj-Cys-Xk, (SEQ ID NO 2), in which Xi is 6 or 12, Xj is 5 and Xk is 6 or 12.

Conclusion

9. No claims are allowed.

Art Unit: 1653

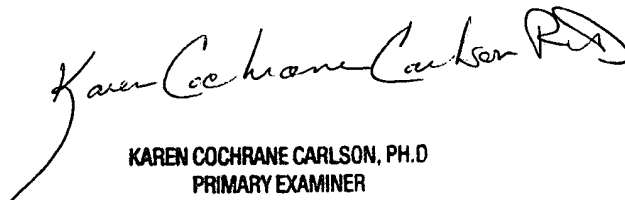
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843.

The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
February 3, 2003


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER